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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,264	09/18/2006	Hajime Kusano	KUSANO 1	6438

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EXAMINER	
RICCI, CRAIG D	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,264	KUSANO ET AL.	
	Examiner	Art Unit	
	CRAIG RICCI	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *4,7,8,14 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-6, 9-13 and 16-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of (i) quercetin glycoside; (ii) cellulose; (iii) spheres; (iv) saccharide derivatives of α,α-trehalose; and (v) a powder in the reply filed on 01/09/2009 is acknowledged. Applicant traverses on the ground that claims 1, 5 and 6 define subject matter which establish unity of invention. However, as stated in the Requirement for Restriction mailed on 12/09/2008, each carrier, vitamin glycoside, and pharmaceutically acceptable substance is distinct, having distinct properties and attributes, and thus various combinations of said components provide distinct products with lack a common special technical feature. For example, in addition to applicant's elected cosmetic powder, the claims encompass a toothpaste comprising a functional powdery product (wherein the carrier is protein fibers and the vitamin glycoside is L-ascorbic acid 2 glycoside), which is distinct from the elected compound specie. Furthermore, for the reasons discussed below, the technical feature of the elected compound species is not special. Accordingly, the requirement is still deemed proper and is therefore made FINAL.

2. The elected species read upon claims 1-3, 5-6, 9-13 and 16-20.

3. Claims 4, 7-8 and 14-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 01/09/2009.

Priority

4. The earliest effective filing date afforded the instantly claimed invention has been determined to be 03/14/2005, the filing date of PCT/JP05/04476 of which this Application is a U.S. National Stage Application submitted under 35 U.S.C. 371.

5. Acknowledgment is made of Applicant's claim for foreign priority pursuant to 35 U.S.C. 119(a) and 365(b) based on a prior application filed in Japan on 03/17/2004. The certified copy has been filed in parent Application No. PCT/JP05/04476, filed on 03/14/2005. Applicant has not been granted the benefit of foreign priority under 35 U.S.C. 119(a)-(d) because a certified English translation of the foreign application has not been provided.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. **Claims 1-3, 5-6, 9-10 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Shefer et al* (2003/0232091), *Allen et al* (Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, Page 264, 2004), *Szycher* (High Performance Biomaterials: A Complete Guide to Medical and Pharmaceutical Applications, Pages 625-626, 1991) and *Greers et al* (US 2003/0170186).**

9. Instant claims 1-3, 5-6 and 9 are drawn to a functional powdery product which is prepared by allowing a carrier (specifically, cellulose in the form of a sphere) to support a vitamin glycoside (specifically, quercetin glycoside) and instant claims 10 and 18-20 are drawn to an external dermatological agent in the form of a powder comprising the functional powdery product of claim 1.

10. Cosmetic compositions (i.e., external dermatological agents) comprising spherical powders are well known in the art. For example, *Shefer et al* teach stabilized retinol for cosmetic, dermatological and pharmaceutical compositions (Title). More specifically, *Shefer et al* disclose "a composition formed of hydrophobic micospheres or particles encapsulating retinol" (Paragraph 0079) which "can be incorporated into any cosmetic, dermatological, or pharmaceutical compositions known in the art, including liquids, **powders**, gels, lotions, creams, sprays, sticks, ointments and pastes" (Paragraph 0081, emphasis added). Furthermore, *Shefer et al* teach that the stabilization of the retinol by allowing the microsphere to support it "sustains the release of retinol during the product shelf life" (Paragraph 0002) and "guarantee the results desired in storing and handling these [cosmetic, dermatological, or pharmaceutical]

compositions" (Paragraph 0065), thus overcoming retinol's "sensitivity to oxidation" which prevents the widespread use of retinol in cosmetic and dermatological compositions (Paragraph 0009). Accordingly, *Shefer et al* teach a cosmetic in the form of a powder comprising a functional powdery product which is prepared by allowing a carrier to support a compound. However, *Shefer et al* do not teach functional powdery products **(1)** wherein the carrier is cellulose and **(2)** wherein the carrier supports quercetin glycoside as encompassed by the instant claims.

11. As to (1): *Shefer et al* do not teach functional powdery products wherein the carrier is formed from cellulose. Rather, the microspheres taught by *Shefer et al* are preferably formed from hydrophobic materials such as glyceryl monostearate, GANEX® V-220 and GANEX® WP-660 (Paragraph 0090). Nevertheless, it would have been obvious to a person of ordinary skill in the art to use cellulose microspheres as the carrier in the invention taught by *Shefer et al*. As disclosed by *Allen et al*, "[t]he rate of drug release from solid dosage forms may be modified by technologies" such as placing the drug "on microcrystalline cellulose spheres" (Page 264, Column 1) and, furthermore, *Szycher* teaches that "[m]icrospheres having different hydrophobicities can be prepared by conversion of the hydrophilic surfaces of cellulose microspheres into hydrophobic ones by allowing alkyl amines of different carbon number or aromatic and cylcoaliphatic amines to link to the cellulose microspheres using the CNBr activation method" (Page 625, Column 2 – Page 626, Column 1). Thus, as evidenced by *Allen et al* and *Szycher*, hydrophobic cellulose microspheres useful for modifying drug release are well known in the art and it would have been *prima facie* obvious to a person of ordinary skill in the art

at the time the invention was made to substitute one known microsphere binder (cellulose) for another (glyceryl monostearate) to obtain a carrier providing predictable results. As stated by the Court in *KSR International Co., v. Teleflex Inc.*, 82 USPQ2d 1385 (US 2007), "when a patent 'simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious'" quoting *Sakraida v. AG Pro Inc.*, 425 U.S. 273 (1976). Since the carrier formed from cellulose provides the same function as the carrier formed from glyceryl monostearate taught by the prior art, and furthermore yields no more than one would expect from such a carrier, the cellulose carrier is obvious.

12. As to (2): *Shefer et al* do not teach functional powdery products wherein the carrier supports quercetin glycoside. Rather, as discussed above, the microspheres taught by *Shefer et al* support retinol. Nevertheless, it would have been obvious to a person of ordinary skill in the art to use quercetin in place of retinol in invention taught by *Shefer et al*. As disclosed by *Geers et al*, "[e]fforts at cosmetically treating the effects of stress-induced aging of the skin have targeted the reduction of MMP-1 activity or the increased synthesis of collagen. The use of retinic acid or retinol is said to reduce the synthesis of MMP-1 in the skin or to increase the synthesis of collage. However, the use of retinic acid for cosmetics is not permitted in Europe because of teratogenic properties" (Paragraph 0019). Accordingly, *Geers et al* disclose cosmetics comprising flavone (including quercetin) glycoside derivatives (Paragraph 0008) which "provide low side effect, highly effective substances which would be easy to process and to apply"

(Paragraph 0020). Thus, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to replace retinol in the composition taught by *Shefer et al* with quercetin glycoside. The skilled artisan would have been motivated to do so in order to eliminate the teratogenic properties inherent in the composition taught by *Shefer et al* and thus allow for the product to be marketed in Europe. In view of *Geers et al*, the person of ordinary skill in the art would have reasonably predicted that replacing retinol with quercetin glycoside would provide a cosmetic powder having the same beneficial properties as the composition taught by *Shefer et al* without the teratogenic properties, and would thus be able to be marketed in Europe.

13. Thus, for all of the foregoing reasons, instant claims 1-3, 5-6, 9-10 and 18-20 are rejected as *prima facie* obvious.

14. **Claims 11-13 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Shefer et al* (2003/0232091), *Allen et al* (Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, Page 264, 2004), *Szycher* (High Performance Biomaterials: A Complete Guide to Medical and Pharmaceutical Applications, Pages 625-626, 1991) and *Greers et al* (US 2003/0170186) as applied to claims 1 and 10 above, in further view of *Tanabe et al* (WO 2004/071472) for which US 2007/0003502 is being used as the English language equivalent.**

15. Instant claims 11-13 and 16-17 are drawn to the external dermatological agent of claim 10, which further comprises one or more pharmaceutically acceptable substances, specifically saccharide derivatives of α, α-trehalose.

16. *Tanabe et al* teach a "skin preparation for external use characterized by containing sugar derivative of α,α-trehalose" (Title). More specifically, *Tanabe et al* teach that the external dermatological formulations include "powders" (Paragraph 0006) and the saccharide derivatives of α,α-trehalose include "α-maltotriosyl α,α-trehalose" (Paragraph 0008). Furthermore, *Tanabe et al* explicitly teach a powder foundation comprising saccharide derivatives of α,α-trehalose (specifically 2.1% "α-maltotriosyl α,α-trehalose (*see* Paragraph 0070, Example 3 which was further processed to the amorphous powder in Example 7, Paragraph 0100, which was used in the powder foundation)) which "is capable of freshly making up and satisfactorily keeping the makeup by moisturizing effect of saccharide derivatives of α,α-trehalose and has a satisfactory skin feeling without sticky feeling" (Paragraph 0115, Example 20). Additionally, *Tanabe et al* teach a cleansing powder comprising saccharide derivatives of α,α-trehalose (specifically 1.6% "α-maltotriosyl α,α-trehalose (*see* Paragraph 0073, Example 6 which was used in the cleansing powder)) which had effects on "treating and preventing aging of skins... advantageously used for preventing stimulation or itch of skins, and treating or preventing aging of skins. Since the product has a satisfactory moisturizing effect given by the saccharide derivatives fo α,α-trehalose in spite of without glycerin, it is a cleansing powder having a satisfactory skin feeling without tightening feeling after applied" (Paragraph 0146, Example 37).

17. Accordingly, it would have been *prima facie* obvious to include saccharide derivatives of α,α-trehalose (specifically, for example, α-maltotriosyl α,α-trehalose) in the *prima facie* obvious powder cosmetic taught by the prior art. The skilled artisan

would have been motivated to include saccharide derivatives of α,α-trehalose in view of *Tanabe et al* who teach numerous advantages of including saccharide derivatives of α,α-trehalose in cosmetic powders such as providing an enhanced skin feeling effect, moisturizing effect, and for treating aging of skins. A person of ordinary skill in the art would have thus included the saccharide derivatives of α,α-trehalose in the prima facie obvious cosmetic powder in order to achieve these desired effects and with a high degree of predictability.

18. Furthermore, as stated in MPEP 2144.06, "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626, F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). In the instant case, *Shefer et al* teach compositions which are useful for treating the skin and the skilled artisan would reasonably predict that the *prima facie* obvious cosmetic composition would similarly be useful for treating the skin. Thus, it would have been *prima facie* obvious to combine saccharide derivatives of α,α-trehalose (which are useful for treating the skin) in the prima facie obvious cosmetic powder for treating the skin in view of *In re Kerkhoven*.

19. Accordingly, claims 13 and 16-17 are rejected as *prima facie* obvious. Additionally, claim 12 is also rejected since saccharide derivatives of α,α-trehalose have the various effects recited by instant claim 12 such as a blood-flow promoting effect as evidenced by *Tanabe et al* (Abstract).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571) 270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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